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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,924	05/20/2002	Roger Johansson	1501-1007	9945

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EXAMINER

BIANCO, PATRICIA

ART UNIT PAPER NUMBER

3762

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/030,924

Applicant(s)

JOHANSSON, ROGER

Examiner

Patricia M Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/20/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to because of the following minor informalities:  
with respect to figure 4, the lines from reference numerals 411, 416 & 419 are not solid and therefore do not distinctly point out the referenced structures; at the proximal end of the figure (top of sheet 3), it appears that there is an arrow without a reference number pointing into the first tube

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference character(s) mentioned in the description:

reference number 115 is not shown on figure 1c, as indicated on p. 7, line 5;

reference number 221 is not shown on figure 1b, as indicated on p. 6, line 25;

reference number 211 is not shown on figure 1b, as indicated on p. 6, line 28-9.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:

reference numbers 41, 420 & 421 are shown on figure 4, but are not mentioned in the description.

Corrected drawing sheets, or amendment to the specification to add the reference character(s) in the description, are required in reply to the Office action to

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avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it contains the legal phraseology "comprising" and "said". Correction is required. See MPEP § 608.01(b).

***Claim Objections***

5. Claims 1, and thereby its dependent claims 2-8, are objected to because of the following informalities:

(i) in claim 1, line 7, applicant adds a limitation beginning with "characterized by the distal end of the space..." to further limit the claim to have a characteristic that allows for non-invasive examination of the distal end's location. It is unclear what structure is being "characterized", is it the tube, tip or the inlet and outlet means?

(ii) in claim 5, the "plug" is not positively claimed, but rather is recited in a process-by-process limitation.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 8 recites the limitation "said position indicating object" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 6 recites the limitation "the x-ray opaqueness necessary" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

87. Claim 7 recites the limitation " the x-ray opaqueness necessary" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

9. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, beginning in line 7, the limitation of the "space (118) being sealed in the presence of a position indicating object (130,410) imparting such characteristics to the distal part" is confusing. Does the space impart or indicate the location? Is applicant attempting to positively claim a distinct structure that is a position indicating object? Is the limitation "in the presence" imparting a process of making the sealed space?

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5 & 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hernandez (5,106,365). Hernandez discloses a dialysis probe 1 having a tubular dialysis membrane 7 that is within and supported between a sheath 2. The sheath may be sealed at the distal end with a resin plug 15 (see figure 4) or the end may be sealed with a closed end 14 that is filled with air (see figure 3) by means of heat sealing. The sheath is formed by two tubes 3 & 4 for inlets and outlets of perfusion fluid, which thereby defines a first tube and a space is arranged about the membrane to allow

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perfusion liquid to move therebetween. Since the free end of the probe is sealed, this seal will inherently allow for non-invasive examination of the distal location or position.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4, 6 & 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hernandez ('365) in view of Gillies et al. (6,272,370). Hernandez discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the position indicating object is selected from the following: an x-ray opaqueness giving object, an object made from gold, an object visible when using NMR, or a plug made of bio-compatible metal, alloy, amorphous compound, or of a glue with a dispersed compound therein to impart x-ray opaqueness.

Gillies discloses a microcatheter, such as a microdialysis probe, having distal markers 6 made of radio-opaque and MR-visible materials, such as gold, platinum or tantalum, to provide easily identifiable reference points for trackability and localization under MR imaging and x-ray. Col. 25, lines 12-67. It would have been obvious to one having ordinary skill in the art, at the time the invention was made, to modify the plug on the probe of Hernandez to be made of a radio-opaque and MR-visible materials, such as gold, platinum or tantalum, to provide easily identifiable reference points for ease in



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tracking and localizing the probe's tip under MR imaging and x-ray, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

### ***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Patsalos et al. (5,607,390) and Liska et al. (2003/0236454 A1) disclose similar microdialysis probes.

Patsalos et al. discloses a probe having a plug at the distal end.

Liska et al. discloses a probe having multiple fluid passageways.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 24<sup>th</sup>, 2004

Patricia M Bianco  
Primary Examiner  
Art Unit 3762



**PATRICIA BIANCO**  
**PRIMARY EXAMINER**